IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

DALE BAUER, CHRIS CHARLES, MITCHELL CHARLES, BODY DALLE, DANIEL GUNTER, d/b/a Gunter Honey, Inc., JUSTIN KENT, d/b/a Kent Honey Bees, Inc., GARY MACKRILL, JOSE MORENO, d/b/a Oro Dulce, Inc., DAVID PARK, DEWEY ROBINSON, KENNETH SHEARON, ELAINE THOMPSON, JEREL JOHNSON, Plaintiffs	:	
v.	:	3:CV-03-1687
	:	(JUDGE VANASKIE)
BAYER A.G., BAYER CORPORATION, Defendants	:	

MEMORANDUM

This action arises out of the alleged exposure of honeybees to imidacloprid, the active ingredient in the insecticide Gaucho, which purportedly caused death in Plaintiffs' honeybees and a substantial decrease in their honey production. Thirteen (13) Plaintiffs, Dale Bauer, Chris Charles, Mitchell Charles, Body Dalle, Daniel Gunter (d/b/a Gunter Honey, Inc.), Justin Kent (d/b/a Kent Honey Bees, Inc.), Gary Mackrill, Jose Moreno (d/b/a Oro Dulce, Inc.), David Park, Dewey Robinson,[1] Kenneth Shearon, Elaine Thompson, and Jerel Johnson, who own or formerly owned honeybees and honeybee hives, brought suit against Bayer A.G., Bayer Corporation, Bayer Cropscience A.G., and Bayer Cropscience LP (collectively referred to as

[1]It appears that this Plaintiff is actually Dewey Beals Robson. See Aff. of Dewey Robson, Dkt. Entry 95-10.

"Bayer"), asserting claims of negligence, strict liability, and breach of warranty premised upon the contention that Gaucho, produced by Bayer, decimated their bee population.

Before the Court are Bayer's Motion for Summary Judgment (Dkt. Entry 86), Motion to Exclude the Chemical Analyses of ADPEN (Dkt. Entry 88), and Motion to Exclude the Opinion Testimony of Daniel F. Mayer, Ph.D. (Dkt. Entry 89.)[2] The Motion to Exclude the Chemical Analyses of ADPEN will be granted as to the initial analysis showing elevated levels of imidacloprid in bees and honeycomb because Plaintiffs have not shown that the testing protocol employed by ADPEN was scientifically sound. To the extent that Dr. Mayer relied upon ADPEN's initial analysis in propounding his opinions on a causal relationship between imidacloprid and bee losses, his opinion testimony will be stricken. To the extent that Dr. Mayer opines that bee losses could be attributed to much lower levels of imidacloprid found during subsequent analyses of honey and wax conducted by ADPEN, his opinion testimony lacks adequate scientific support. As a result, Plaintiffs have not tendered sufficient evidence on the question of causation to withstand Bayer's summary judgment motion, and judgment will accordingly be entered in favor of Bayer.

[2] For the convenience of the reader of this decision in electronic format, hyperlinks to the record and authority accessible via the internet have been inserted.

I. BACKGROUND

A. Procedural History

On September 24, 2003, thirteen (13) Plaintiffs filed this lawsuit as a class action. (Dkt. Entry 1.) Defendants filed a Motion for More Definite Statement, which the Court granted, thus requiring Plaintiffs to state with more specificity the allegations supporting class action status. (Ct. Order, Dkt. Entry 19.) Plaintiffs complied and submitted an Amended Complaint on March 10, 2004. (Dkt. Entry 23.)

On June 28, 2004, Defendants Bayer A.G. and Bayer CropScience A.G. moved to dismiss the suit for lack of personal jurisdiction, (Dkt. Entry 30), which the Court granted. (Dkt. Entry 46.) On July 22, 2004, Plaintiffs Justin Kent d/b/a Kent Honey Bees, Inc., Jose Moreno d/b/a Oro Dulce, Inc., and David Park filed a Stipulation of Dismissal as to all Defendants. (Dkt. Entry 32.) On August 31, 2004, Plaintiff Kenneth Shearon likewise filed a Stipulation of Dismissal as to all Defendants. (Dkt. Entry 43.)

On January 25, 2005, the remaining nine (9) Plaintiffs filed a Motion to Certify Class (Dkt. Entry 52), which the Court denied in an Order dated June 7, 2005. (Dkt. Entry 66.) Thereafter, on December 4, 2006, Bayer filed a Motion for Summary Judgment (Dkt. Entry 86), Motion to Exclude the Chemical Analyses Purportedly Conducted by ADPEN (Dkt. Entry 88), and Motion to Exclude the Testimony of Dr. Mayer. (Dkt. Entry 89.) On May 21, 2008, the Court held oral argument on Defendants' pending motions. (Dkt. Entry 108.) These motions

are fully briefed and ripe for resolution.

B. Factual History

1. Plaintiffs' honeybee business

Plaintiffs are involved in the honeybee business. Each Plaintiff owns, or previously owned, thousands of beehives. (Affidavits of Plaintiffs, found at Dkt. Entries 95-3 to -10.) As migratory beekeepers, Plaintiffs move their honeybees across the United States two or three times a year. (Defs.' Statement of Material Facts ("SMF"), Dkt. Entry 86-4, ¶ 13.) During the summer months, the honeybees are kept in North Dakota and other northern states, where they produce honey. While there, the honeybees forage in fields of various crops, including canola. (Id. at ¶ 14.) During the fall and winter months, Plaintiffs transport their honeybees to warmer areas, such as Texas, where they are dormant, or to California, where the honeybees pollinate almond crops. (Id.)

Between the years 1995 and 1999, some Plaintiffs began to notice drastic changes in the condition of their honeybees. These changes consisted of a decrease in the population of their honeybees and honey production, dead honeybees in front of hive boxes at higher rates than before, and an unusually significant number of disoriented honeybees around the hive boxes.[3] (Affidavits of Plaintiffs, found at Dkt. Entries 95-3 to -10.)

[3]In 1999, Chris and Mitchell Charles sustained honeybee losses of up to 60% of their colonies. (Mayer Report, Dkt. Entry 95-2, at 9.)

2. Imidacloprid

Plaintiffs attribute the decimation of their honeybees to the use of imidacloprid to treat canola seeds. Imidacloprid is the active ingredient in Gaucho, an insecticide produced by Bayer. Gaucho is applied through a liquid seed treatment, meaning seeds are coated with Gaucho prior to planting. (Defs.' SMF, at ¶ 7.) This treatment results in imidacloprid spreading throughout the plant as it grows to maturity. (Id.) Then, when insects attack the Gaucho treated plant, the juices in the plant contain a sufficient quantity of Gaucho to kill the insects and protect the plant. (Id.) After receiving approval from the EPA (Environmental Protection Agency), Bayer began selling Gaucho in the United States in 1995. (Defs.' SMF, at ¶ 6.)

The acute LD_{50} of imidacloprid in honeybees, that is, the dose required to cause a 50% mortality rate, is no less than 142 parts per billion (ppb), with a 0% mortality rate at 46 ppb. (Steffens Dep., Dkt. Entry 86-32, at 59-60.) The level of imidacloprid found in the nectar and pollen of a Gaucho-treated crop ranges between zero and 7.6 ppb, well below a lethal dose. (Scott-Dupree Aff., Dkt. Entry 86-41, 11-12.

3. Laboratory Analyses of Imidacloprid

To ascertain the cause of the abnormal behavior and death rate in their honeybees, Plaintiffs Chirs Charles and Mitchell Charles sent samples of dead honeybees and honeycomb to a United States Department of Agriculture ("USDA") laboratory in Weslaco, Texas. (Defs.'

SMF, at ¶ 48.) The USDA was unable to conduct the appropriate tests, and recommended that Plaintiffs contact ADPEN Laboratories, Inc., in Jacksonville, Florida.

At the request of the Charles brothers, the USDA forwarded the samples of honeybees and honeycomb to ADPEN. The Charles brothers later sent additional samples to ADPEN.[4] (Defs.' SMF, at ¶ 48.) ADPEN's testing resulted in a finding of imidacloprid levels of 483.12 ppb, 22.64 ppb, 671.56 ppb, and 136.47 ppb in four samples of dead bees, and 136.47 ppb and 105.33 ppb in two samples of honeycomb. (Defs.' Ex. 47, Dkt. Entry 86-53.) Significantly, however, ADPEN reported that a control sample, assumed to be free from any chemical exposure, contained 153.60 ppb imidacloprid. (Defs.' Ex. 51, Dkt. Entry 86-57; Defs.' Ex. 52, Dkt. Entry 86-58, at 2.)

Bayer CropScience scientists obtained the raw data used by ADPEN and identified what they believed to be methodological and other problems with ADPEN's testing. (Defs.' SMF, at ¶ 52.) Dr. William Leimkuehler, a principal scientist employed by Bayer CropScience, made the following remarks:

> My opinion is that the testing done by Adpen was not performed using proper analytical procedures for imidacloprid which resulted in generation and premature reporting of unreliable and false results. Some of the analytical processes performed were done without fully considering the physiochemical properties of imidacloprid. In addition, the procedures employed had not undergone rigorous reproducibility and reliability testing required for a validated analytical method. As a result of these issues, irreproducible and

[4]It is unclear whether these samples included wax from Dewey Robson. (Defs.' SMF, at ¶ 50.)

unreliable data was produced.

(Leimkuehler Report, Dkt. Entry 86-34, at 2.)

In particular, Dr. Leimkuehler highlighted five areas of concern in ADPEN's initial analysis. First, in his opinion, "the chromatography associated with the tandem mass spectrometry (LC/MS/MS) analysis was very poor."[5] (Id. at 2.) The retention times reported by ADPEN were not consistent with the expected retention time of imidacloprid. "[I]midacloprid should have been retained for 10-12 minutes on the column," and not 2.3 minutes as reported by ADPEN. (Id.)

Second, according to Dr. Leimkuehler, analytical literature reports that the 209 Atomic Mass Unit (amu) fragment is the most commonly measured fragment when analyzing imidacloprid, not the 239 amu fragment used by ADPEN. (Id. at 3.) Since the measured fragment is generally proportional to the amount of pesticide in the sample, only fragments unique and specific to the pesticide should be measured. Dr. Leimkuehler is of the opinion that the 239 amu fragment is a minor, obscure background fragment in the spectrum of fragments contained in imidacloprid. (Id.)

---

[5]Chromatography refers to a process of separating and identifying substances dissolved in a mixture or solution by slow passage through a tube or over a surface adsorbing material (such as clay, silica gel, or alumina or on paper), with each substance being separated either as colored bands or by differences in speed of travel when processed through the adsorbing material. WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 401 (1993). Liquid Chromatography Tandem Mass Spectrometry (LC/MS/MS) is an analytical technique for pesticide residue analyses. (Ex. 28, Dkt. Entry 86-34, at 2.)

Third, Dr. Leimkuehler questioned the response of imidacloprid during the testing. (Id.) The response of a target compound should be proportional to the amount injected so a linear calibration curve can be constructed. ADPEN's calibration curve showed a 4,328,551 and 2,371,931 response (for two separate injections) for .5 nanograms (ng) and 2,825,542 for 50 ng. To be linear, the response for 50 ng should have been 100 times that of .5 ng. (Id.) According to Dr. Leimkuehler, "it would be impossible to assign an accurate residue value for imidacloprid with the variable and irreproducible data used to construct" ADPEN's calibration curve. (Id. at 4.)

Fourth, the control sample contained residues of imidacloprid at nearly the same levels as the other samples, while the control sample was assumed to lack imidacloprid. Dr. Leimkuehler suggested that other molecules were interfering, perhaps mistakenly being measured as imidacloprid, thus complicating the QC (quality control) samples. Finally, Dr. Leimkuehler opined that Gas Chromatography (GC) is not widely attempted or recommended for the analysis of imidacloprid because it produces signals too unreliable for accurate quantitative determinations. (Leimkuehler Report, Dkt. Entry 86-34, at 2.)

Rolando Perez, President and Technical Director of ADPEN, responded to Bayer's review of ADPEN's analysis in a letter dated October 21, 2001. (Ex. 52, Dkt. Entry 86-58.) He stated that, in the analysis, ADPEN simultaneously analyzed the samples in question for four (4) pesticides: Gaucho (imidacloprid), Admire (imidacloprid), Furadan (carbofuran) and Vapona

(dichlorovos). Thus, according to Mr. Perez, "the chromatography was not optimized for imidacloprid." (Id.) ADPEN resorted to a modified version of the LC/MS/MS analysis used for the chromatography of coumaphos because "there were no other methods available for the analysis of these pesticides in honeybees, not even from the EPA." (Id. at 2.) Mr. Perez observed that ADPEN was "not contracted to develop a procedure, but to help determine what was killing the bees as best [it] could with the available methodology and in a short amount of time." (Id.)

Mr. Perez further indicated that he had informed both Bayer and Mr. Charles that "due to possible matrix effects that could affect the chromatography on the LC/MS/MS instrument, the residue reported could be lower or higher than that reported." (Ex. 52, Dkt. Entry 86-58, at 3.) Nevertheless, Mr. Perez noted the positive increases in responses in the honeybee samples versus a control honeybee from the same area and confirmed the presence of imidacloprid in the honeybee samples by GC and LC/MS/MS. (Id. at 3.)

In the final paragraph of his letter, Mr. Perez referred to a conference call between ADPEN and Bayer, during which they decided "that the best course of action was to analyze honeybee samples with Bayer's method, which was optimized for determination of imidacloprid in honeybees." (Id.) Mr. Perez acknowledged that this course of action would provide a final and more appropriate answer to the questions at hand and concluded that all additional tests should be conducted with the method that Bayer recommended. (Id.)

ADPEN subsequently analyzed other samples of honeycomb, using many of Bayer CropScience's suggestions on how to test for imidacloprid. (Defs.' SMF, at ¶ 54.) ADPEN first conducted an analysis of honeycomb for Kenneth Shearon Bee Farms, the results of which are found in test results dated February 11, 2002.[6] (Ex. 49, Dkt. Entry 86-55, at 2.) The analysis found undetectable amounts of imidacloprid in the "Wax Brood Area," and .5 ppb in the "Comb from honey area." (Id.) ADPEN also conducted an analysis of samples of honey and honeycomb for Mitchell Charles, finding, in results dated March 2, 2002, imidacloprid residue of 0.83 ppb in honey and 3.2 ppb in wax. (Defs.' Ex. 48, Dkt. Entry 86-54, at 2.) Finally, ADPEN conducted a test for Robson Honey Company for honeycomb samples submitted in June of 2003. (Ex. 50, Dkt. Entry 86-56, at 2.) In the analysis result dated September 3, 2003, ADPEN reported that imidacloprid was "not detected" in two samples of honeycomb, and 1.3 ppb of imidacloprid was found in a third sample. (Id.)

Dr. Leimkuehler found the studies conducted by ADPEN in March of 2002 "much more in agreement with all previously published results" because ADPEN had incorporated many of Bayer CropScience's suggestions. (Leimkuehler Report, Dkt. Entry 86-34, at 5.) Specifically, Dr. Leimkuehler made the following observations: ADPEN employed a more acceptable LC/MS/MS method, resulting in a retention time of imidacloprid of approximately 11 minutes as opposed to 2.3 minutes; by using the 209 amu fragment in the MS/MS analysis instead of the

[6]As noted above, Kenneth Shearon dismissed his claims against Bayer.

239 amu fragment, ADPEN made the responses to the calibration curve proportional; only a small signal in the blank was created at the expected imidacloprid retention time; ADPEN prepared QC samples for every matrix; and ADPEN reported reasonable, reproducible recoveries. (Id.)

4. Plaintiff's Expert

In July of 2003, Dr. Daniel F. Mayer traveled to North Dakota and investigated seventeen (17) different apiaries (yards in which honeybees are kept) owned by a few of the Plaintiffs. (Mayer Report, Dkt. Entry 95-2, at 11.) He also discussed with Chris and Mitchell Charles the unexplained deaths of their honeybees. (Id. at 10.) In general, Plaintiffs observed substantial bee losses when hives were placed in boxes, known as "honey supers," or "supers." (Mackrill Dep. of 7-9-04 at 47-49, Bauer Dep. of 7-29-04 at 80; Christian Charles Dep. of 5-22-06 at 150, 153; Christian Charles Dep. of 7-6-04 at 91-96; Gunter Dep. of 5-26-06 at 61-62.) There is testimony that losses were not experienced when hives were either left uncovered with supers or were covered with previously unused supers. (Christian Charles Dep. of 7-6-04 at 99-100.) Thus, contamination of the supers, which contain the wax, was suspected.

As a result of his discussions and investigation, Dr. Mayer formulated the following theory to explain how Gaucho negatively impacts honeybees:

> Canola seed treated with Gaucho is planted and the systemic insecticide imidacloprid moves up the plant and is present in the flowers of canola. Honeybees foraging on the contaminated flowers for nectar and pollen pick up the imidacloprid and take it back to the hive. The nectar is

> converted to honey. Both the honey and the pollen are stored in the wax combs in the honey supers. Imidacloprid moves from the honey and pollen into the wax combs. The imidacloprid residues build up in the wax combs and after two years of field use there is sufficient imidacloprid in the wax combs to cause bees to behave erratically and die.

(Mayer Report, Dkt. Entry, 95-2, at 10.)[7]

Dr. Mayer claims he "personally knows that many of the canola fields in the Carrington area of North Dakota were planted with seed treated by Gaucho."[8] (Id. at 11.) Of the colonies that Dr. Mayer claims to contain imidacloprid-contaminated supers, he personally observed 300-600 fresh dead adult honeybees in front of each colony, adult bees crawling and twitching, and no stored honey. Those colonies with purportedly uncontaminated supers, however, contained 5 to 10 adult bees dead in front of each colony, normal behaving bees, and stored honey. (Mayer Report, at 11.)

The following November, Dr. Mayer again visited Carrington, North Dakota to discuss

---

[7]Dr. Mayer describes how the imidacloprid moves from the honey and pollen to the wax in the following manner:

> [The imidacloprid moves] through that thin film of moisture that surrounds the wax. It becomes concentrated in there, in a dark, wet environment. The humidity is really high in there. The temperature is maintained at ninety-some degrees, and it's just sitting in there on the wax, in the wax and on the edge of the wax.

(Mayer Dep., at 193.)

[8]While in North Dakota, Dr. Mayer saw the map of a chemical and insecticide distributor. The map apparently identified the fields treated with Gaucho. (Dep. Mayer, Dkt. Entry 86-33 , at 149-50.)

the deaths of honeybees with Chris and Mitchell Charles and inspect their apiaries. (Id.) In Dr. Mayer's opinion, of the twenty-one colonies he inspected, seventeen contained bees suffering from the effects of imidacloprid. Eight had 400-500 fresh dead bees and nine had 1,000 dead bees on the bottom board. At his third visit on August 24, 2004, Dr. Mayer asserts that he observed the typical symptoms of imidacloprid poisoning in the bee colonies of Chris Charles, Mitchell Charles, Lonnie Thompson and Dewey Robson. (Id.)

Dr. Mayer collected samples of honeybees and wax frames from Plaintiffs, intending to submit them to a lab in California for chemical analysis. (Mayer Dep., Dkt. Entry 86-33, at 61-62.) The chemical analysis, however, did not occur because Dr. Mayer never received the "go ahead" from Plaintiffs. (Id. at 62.) Consequently, Dr. Mayer stored the samples in his freezer for three years and then moved them into his garage. After they spoiled and started to emit unpleasant odors, he discarded them. (Id.)

Dr. Mayer's investigation included the inspection of bee colonies belonging to Plaintiffs Chris Charles, Mitchell Charles, Dale Bauer, Lonnie Thompson and Dewey Robson. (Mayer Report, at 16.) As a result of his visits, Dr. Mayer concluded that "each beekeeper was suffering excess loss of honeybees and honey production as a direct result of imidacloprid contamination." (Id.) Dr. Mayer based his opinion on his observations, the Plaintiffs' statements as to the disoriented behavior of the bees and large amount of dead bees outside the supers, and the ADPEN lab results that found high levels of imidacloprid in dead bees and

honeycomb from Plaintiffs' colonies. He also based his opinion on the premise that imidacloprid "at very low ppb has a sublethal negative effect on honeybees," which "over time can be very detrimental to the colony." (Id. at 17.)

5. Defense Experts

It is undisputed that the "No Observable Adverse Effect Concentration" (NOAEC) for imidacloprid in honeybees is 20 ppb, meaning that no adverse effects on honeybees have been observed at concentrations at or below 20 ppb. (Defs.' SMF, at ¶ 58.) Although Plaintiffs baldly assert that the NOAEC lacks "scientific basis validating that the [NOAEC] means that the pesticide is truly not harming bees," (Plaintiffs' SMF, at ¶ 40), Defendants have cited an impressive array of studies to the contrary. For example, Cynthia D. Scott-Dupree, Ph.D., observed:

> In validated scientific controlled feeding experiments Kirchner (1998, 2000) and Schmuck et al. (2001) established and reconfirmed the "no observable adverse effect concentration" (NOAEC) of imidacloprid for honey bees at 20 parts per billion (ppb) or 20 ug/L. The NOAEC is defined as the maximal or near-maximal concentration or dose at which no difference from untreated or solvent-treated controls is detected (Perry et al. 1998). In Kirchner's studies the impact of imidacloprid concentrations between 10 and 100 ppb on communication of food source location, foraging activity, population strength and breeding performance was investigated. At test concentrations from 10-20 ppb there was no difference between any of these variables and the untreated controls. At concentrations of $\geq$ 20 ppb honey bees showed a lower motivation to perform waggling dances (i.e. to recruit siblings to a food source) and at concentrations $\geq$ 50 ppb there was delayed-transitory disruption in foraging activity compared to untreated controls. In a 39-day chronic feeding study with sunflower pollen and nectar fortified with imidacloprid concentrations between 2 and 20 ppb, Schmuck et al. (2001) showed no adverse effect on bees in terms of mortality, feeding activity,

> wax/comb production, breeding performance and colony vitality, even at the highest concentrations. Faucon et al. (2005), in a long-term chronic feeding that followed colonies from July, 2000 to March 2001 fed sugar syrup fortified with either 5 or 50 ppb of imidacloprid also found no adverse effect on bees in terms of adult bee activity, adult population level, capped brood area, frequency of parasitic and other diseases, mortality and number of frames of brood after wintering.

(Dr. Scott-Dupree Aff. of Feb. 21, 2005, Dkt. Entry 86-41, at 10-11.)

As noted above, imidacloprid found in the nectar and pollen of Gaucho-treated crops has not exceeded 7.6 ppb. Dr. Scott-Dupree concluded:

> The scientifically valid NOAEC of imidacloprid for honey bees is 20 ppb. Of all the scientifically valid studies conducted to determine imidacloprid residues in sunflowers, maize and canola pollen and nectar - the highest residue levels for each are considerably lower than the established NOAEC - therefore, no adverse effect will result when honey bees forage on sunflower, maize and canola grown from seed treated with imidacloprid at recommended label field rates.
> The mere presence of a pesticide in a substrate does not means [sic] that deleterious impacts to non-target organisms will occur. If residue values are below the established NOAEC for a particular pesticide no deleterious impact will occur.

(Id. at 13; emphasis in original.)

Based in large measure upon the defects in initial laboratory analyses performed by ADPEN and the imidacloprid NOAEC for honeybees, Bayer challenges the admissibility of Dr. Mayer's opinions. If Dr. Mayer's conclusions are inadmissible, then Plaintiffs cannot withstand Bayer's summary judgment motion. Accordingly, the issue of admissibility of the lab results and Dr. Mayer's opinions will be assessed first.

II. DISCUSSION

A. Motions to Exclude the Chemical Analyses of ADPEN (Dkt. Entry 88), and to Exclude the Opinion Testimony of Daniel F. Mayer, Ph.D. (Dkt. Entry 89)

Rule 702 of the Federal Rules of Evidence, consistent with Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 590 (1993), provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

The trial judge is to act as a gatekeeper to make sure that all expert testimony or evidence is both relevant and reliable. Daubert, 509 U.S. at 589. Where, as here, "the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue," id. at 592, the trial judge must ascertain whether the expert's conclusions are grounded in the "methods and procedures of science. . . ." Id.

"'[K]nowledge' connotes more than subjective belief or unsupported speculation." Id. In other words, "testimony must be supported by appropriate validation- i.e., 'good grounds,' based on what is known." Id. "Put differently, an expert opinion must be based on reliable methodology and must reliably flow from that methodology and the facts at issue – but it need not be so persuasive as to meet a party's burden of proof or even necessarily its burden of

production." Heller v. Shaw Industries, Inc., 167 F.3d 146, 152 (3d Cir. 1999). As explained in Jaasma v. Shell Oil Co., 412 F.3d 501, 513 (3d Cir. 2005), a qualified expert's "testimony (1) must be based on sufficient facts and data; (2) must be the product of a reliable methodology; and (3) must demonstrate a relevant connection between that methodology and the facts of the case."

In evaluating whether a particular scientific methodology is reliable, or scientifically valid, a district court should take into account the following factors, as well as any others that are relevant:

> (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.

In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 742 n.8 (3d Cir. 1994); Daubert, 509 U.S. at 593-94.

"'The reliability requirement must not be used as a tool by which the court excludes all questionably reliable evidence.'" Paoli, 35 F.3d at 744. "The 'ultimate touchstone is helpfulness to the trier of fact, and with regard to reliability, helpfulness turns on whether the expert's technique or principle [is] sufficiently reliable so that it will aid the jury in reaching accurate results.'" Id. (citations omitted). Thus, the question is not whether the expert's conclusions are

correct or rest on the "best foundation, but rather whether any particular opinion is based on valid reasoning and reliable methodology." Kannankeril v. Terminex International, Inc., 128 F.3d 802, 806-07 (3d Cir. 1997). "[A]lthough principles and methodology remain the focus of a Daubert inquiry, 'this focus need not completely pretermit judicial consideration of an expert's conclusions.'" In re TMI Litig., 193 F.3d 613, 682 (3d Cir. 1999).

Rule 702 is governed by Fed. R. Evid. 104(a), which requires a judge to make "'a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid,' and thus enables the judge to exclude evidence presented in plaintiffs' prima facie case." Id. at 743 (quoting Daubert, 509 U.S. at 599). At this stage of the case, Plaintiffs need only demonstrate by a preponderance of evidence that Dr. Mayer's opinions are based on "good grounds." See Kannankeril, 128 F.3d at 806. In assailing Dr. Mayer's conclusions, Bayer contests both the ADPEN lab results he considered as well as the methodology he employed.

1. The ADPEN Results

Defendants contend that Dr. Mayer could not consider the ADPEN analyses because they are inadmissible hearsay. Plaintiffs counter by arguing that under Fed. R. Evid. 703 experts are permitted to rely on hearsay in their reports.[9] (Pls.' Br. Opp'n Defs.' Mot. Exclude

[9]Defendants also challenge the authenticity of the ADPEN analyses under Federal Rule of Evidence 901(a). The standard for authentication of documents was expressed in Link v. Mercedes-Benz of North America, 788 F.2d 918 (3d Cir. 1986):

ADPEN Analyses, Dkt. Entry 93, at 3.)

"While [Rule] 702 focuses on an expert's methodology, Rule 703 focuses on the data underlying the expert's opinion." Paoli, 35 F.3d at 747. Federal Rule of Evidence 703 provides:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or

---

> [T]he showing of authenticity is not on a par with more technical evidentiary rules, such as hearsay exceptions, governing admissibility. *Rather, there need be only a prima facie showing, to the court, of authenticity, not a full argument on admissibility.* Once a prima facie case is made, the evidence goes to the jury and it is the jury who will ultimately determine the authenticity of the evidence, not the court. The only requirement is that there has been substantial evidence from which they could infer that the document was authentic . . . .

Id. at 928 (citing United States v. Goichman, 547 F.2d 778 (3d Cir. 1976)). Accordingly, "'all that is required is a foundation from which the fact-finder could legitimately infer that the evidence is what the proponent claims it be.'" Id. at 927 (citing McQueeny v. Wilmington Trust Co., 779 F.2d 916 (3d Cir. 1985).

Plaintiffs contend that the analyses conducted by ADPEN are authenticated under Federal Rule of Evidence 901(b)(4), which provides that "appearance, contents, substance, internal patterns, or other distinctive characteristics, taken in conjunction with circumstances," support a finding that the matter in question is what its proponent claims. Fed. R. Evid. 901(b)(4). As Plaintiffs note, each analysis contains a certificate number and is written on ADPEN letterhead. Moreover, the initial ADPEN analysis was discussed and examined by Dr. Mayer and Dr. Leimkuehler. (Leimkuehler Report, Dkt. Entry 86-34, at 4.) Where, as here, "the purported author of a writing carries on a continuing correspondence and transacts business with a particular person in such a way that the business transacted corresponds to the information transmitted by the writings, the circumstances of the correspondence and business tend to authenticate the writing." 5 WEINSTEIN & BERGER, WEINSTEIN'S EVIDENCE, ¶ 901(b)(4)[04], at 901-73. In short, the distinctive characteristics of the ADPEN documents, coupled with the discussions concerning them, are sufficient to demonstrate authenticity. Link, 788 F.2d at 928.

> data need not be admissible in evidence in order for the opinion or inference to be admitted. Facts or data that are otherwise inadmissible shall not be disclosed to the jury by the proponent of the opinion or inference unless the court determines that their probative value in assisting the jury to evaluate the expert's opinion substantially outweighs their prejudicial effect.

"[I]f an expert avers that his testimony is based on a type of data on which experts reasonably rely, that is generally enough to survive the Rule 703 inquiry." Paoli, 35 F.3d at 747 (citing Deluca v. Merrell Dow Pharm, Inc., 911 F.2d 941, 955 n.13 (3d Cir. 1990). Rule 703 likewise "permits experts to rely upon hearsay." Id. at 748. But when "the underlying data are so lacking in probative force and reliability that no reasonable expert could base an opinion on them, an opinion which rests entirely upon them must be excluded." Id. at 748. The standard under Rule 703 is the same as under Rule 702, requiring good grounds establishing the reliability of the data. Id. at 748.

A careful review of the record reveals that the initial ADPEN report of September 21, 2001 is not sufficiently reliable, but that the subsequent analyses satisfy the reliability requirement of Fed. R. Evid. 702. The reliability of the initial ADPEN analysis is undermined by the unexplainable level of imidacloprid found in the control sample (153.6 ppb), especially considering that the control sample was assumed clean and devoid of any imidacloprid. Dr. William Leimkuehler, in a detailed critique, remarked that a finding of such a concentration in the control sample suggests a molecule other than imidacloprid was being measured. Dr. Scott-Dupree affirmed, stating that some type of problem was present in the test method. Dr.

Mayer, likewise, was at a loss to explain such a high level of imidacloprid in the control: "It's unexplained. I can't explain it. I mean it happened." (Mayer Dep., Dkt. Entry 86-33, at 32.)

In addition to the questionable levels of imidacloprid in the control sample, Dr. Leimkuehler opined that other fundamental problems existed. (Leimkuehler Report, Dkt. Entry 86-34.) First, in his opinion, the chromatography associated with the tandem mass spectrometry (LC/MS/MS) analysis was very poor. (Id. at 3.) Second, ADPEN measured the 239 amu fragment instead of the commonly measured 209 amu fragment. Third, the response of imidacloprid was not proportional to the amount injected. (Id. at 4.) And fourth, the Gas Chromatography (GC) method was not widely recommended for the analysis of imidacloprid.[10] (Id.)

Plaintiffs have not proffered testimony of a qualified expert to oppose Dr. Leimkuehler's review. Instead, Plaintiffs insist that Mr. Perez stands by the initial ADPEN results because he never retracted them, and even certified them with his signature. Mr. Perez acknowledged, however, that the chromatography was not optimized for imidacloprid and that Bayer's method would provide a final and more appropriate answer. These acknowledgments by Mr. Perez are inconsistent with Plaintiffs' argument that Mr. Perez stands by and endorses the initial ADPEN analysis. Plaintiffs' argument is also undermined by the fact that ADPEN followed the analytical methodology proposed by Bayer's scientists during their second and third rounds of testing.

---

[10]For a more detailed discussion of Dr. Leimkuehler's review, see supra Section I.B.3.

Moreover, Dr. Mayer is not qualified to testify to the reliability of the ADPEN results. Dr. Mayer stated that he routinely relies upon this type of data in his field of expertise and that the ADPEN analyses are reliable. (Mayer Aff., Dkt. Entry 93-3, at 22.) In his deposition, however, Dr. Mayer acknowledged that he was not a chemist and did not know what Dr. Leimkuehler was disputing. (Mayer Dep., Dkt. Entry 86-33, at 201.)

Plaintiffs further assert that the initial ADPEN analysis is reliable because ADPEN employed the same methodology in identifying coumaphos, another Bayer pesticide, as it employed in identifying imidacloprid. In making this assertion, Plaintiffs rely on the testimony of Richard Rogers, who stated, "Adpen did an initial analysis which reported high levels in bees and honeycomb. And they then did a follow-up which showed very-less than detectable levels or low levels. And they also looked at Coumaphos." It does not logically follow from this testimony that Bayer employed the same method in examining coumaphos as imidacloprid. Furthermore, Dr. Leimkuehler testified that "[t]he fact that the coumaphos method may be valid does not tell us anything about whether ADPEN's attempts to test for imidacloprid are sound." (Leimkuehler Dec., Dkt. Entry 100-5, ¶ 4.)

In summary, the initial ADPEN analysis is unreliable, having been conducted without following proper protocol. Dr. Mayer, therefore, cannot base his opinion on the results of the initial analysis.[11]

[11]Plaintiffs request, in the event the Court finds Dr. Mayer's opinion inadmissible, an additional ninety (90) days to obtain data to support the admission of the ADPEN results. (Pls'

The latter ADPEN analyses, however, are significantly different from the initial analysis, as ADPEN made drastic changes in its methodology.[12] Specifically, ADPEN employed a more acceptable LC/MS/MS method, used a 209 amu fragment in the MS/MS analysis instead of the 239 amu fragment, made the responses to the calibration curve proportional, created only a small signal at the expected imidacloprid retention time, prepared QC samples for every matrix, and reported reasonable, reproducible recoveries. (Ex. 28, Dkt. Entry 86-34, at 2.) Bayer concedes that "ADPEN corrected at least some of the serious flaws present in the initial test methods," and that the later tests were "much more in line with what the literature reports about imidacloprid residues occurring in nature." (Defs' Mem. Supp. Mot. to Exclude ADPEN Analyses, Dkt. Entry 88-2, at 18; see Leimkuehler Report, Dkt. Entry 86-34, at 5.)

Thus, the latter ADPEN results are sufficiently reliable to be considered by Dr. Mayer. The question is whether the subsequent results support Dr. Mayer's conclusion that Gaucho is the source of the decimation of bee colonies reported by Plaintiffs. This issue, in turn, requires

---

Br. Opp'n Defs' Mot. Exclude ADPEN Analyses, Dkt. Entry 93, at 16.) This request comes too late. Plaintiffs have known for a considerable period of time that the ADPEN results were questionable. They had ample opportunity to address the matter during the protracted discovery period. They elected to rely upon Dr. Mayer's wholly conclusory assertion that the results are reliable notwithstanding his complete lack of qualifications concerning analytical methodologies for imidacloprid. Plaintiffs cannot try out one argument, have it rejected, and then try again. Accordingly, Plaintiffs will not be given another opportunity to support use of the initial ADPEN results.

[12]Bayer does not specifically challenge the results of the subsequent rounds of ADPEN analyses, other than claiming the ADPEN reports to be hearsay. (Oral Argument, Dkt. Entry 108, at 2.)

consideration of the causation theories propounded by Dr. Mayer.

2. Dr. Mayer's Theory of Accumulation of Imidacloprid in Supers

Dr. Mayer theorizes that imidacloprid in canola seeds treated with Gaucho migrates into honeybee wax and accumulates in honey supers over a two-year period, ultimately killing the honeybees. According to Dr. Mayer, use of contaminated supers perpetuates the exposure to imidacloprid. (Mayer Report, Dkt. Entry, 95-2, at 10.) The assumption critical to his opinions in this case is that the Plaintiffs' honey supers are contaminated with harmful levels of imidacloprid.

An expert's opinion must be based on methods and procedures of science, rather than on subjective belief or unsupported speculation. Oddi v. Ford Motor Co, 234 F.3d 136, 158 (3d Cir. 2000). Defendants assert that the migration and accumulation aspects of Dr. Mayer's hypothesis are unsupported by literature and uncorroborated by any testing. (Oral Argument, Dkt. Entry 108, at 28-29.) Dr. Mayer based his hypothesis on his personal observations; statements of certain Plaintiffs; and the ADPEN results. (Dep. Mayer, Dkt. Entry 86-33, at 63-67, 194-95.) The linchpin of his conclusions in this case is the accumulation of imidacloprid in the wax inside honey supers. No scientific studies or literature, however, have been cited to support his hypothesis of migration and accumulation.

Moreover, his theory is contradicted by the facts of record as well as a plethora of studies. First, there is the physical fact that "[i]midacloprid is highly water soluble (hydrophilic)

and unable to bio-accumulate in fatty tissue. Also, it is not known to have the ability to accumulate in wax." (Rogers Report, Dkt. Entry 86-37, at 8.) Mr. Rogers cited the results of a study funded by the government of New Brunswick that concluded that wax from hives adjacent to imidacloprid treated canola fields did not have detectable levels of imidacloprid. (Id.) Moreover, while pollen and unripe honey in the hives in the New Brunswick study did contain imidacloprid, the levels were well below the 20 ppb NOAEC. (Id.) The results of this study appear to be consistent with the ADPEN results when appropriate analytical protocols were utilized.

Similarly, Dr. Nancy Ostiguy explained that, as a hydrophilic compound, imidacloprid does not accumulate in wax. (Defs.' Ex. 29, Dkt. Entry 86-35, at 11-12.) She elaborated by noting that imidacloprid, due to its "lipophobic" character, "'prefers' . . . to remain in a water environment rather than a lipid environment." (Id. at 12.) Dr. Scott-Dupree further testified that imidacloprid is attracted to water and not wax, and it would be unusual for it to build up in the honeycomb. (Defs.' Ex. 23, Dkt. Entry 86-29, at 7.)

Plaintiffs do not dispute that imidacloprid is a hydrophilic compound. Instead, Dr. Mayer observes that bees wax is not purely lipophilic, suggesting that it would be possible for imidacloprid to accumulate in what he describes as "wet 'supers'." (Dr. Mayer Aff., Dkt Entry 97-2, at 22.)

Dr. Mayer, however, cannot simply assume that imidacloprid will accumulate in

honeybee wax without some scientific basis or validating methodology. In re TMI Litig., 193 F.3d 613, 677 (3d Cir. 1999) (noting that while testimony will not be precluded because it is based on an assumption, "the supporting assumption must be sufficiently grounded in sound methodology and reasoning to allow the conclusion it supports to clear the reliability hurdle."). Notably, Dr. Mayer had recommended sending wax to a laboratory in California that he said was "comfortable doing imidacloprid residues," but never obtained the authorization to do so from Plaintiffs. (Mayer Dep., Dkt. Entry 86-33, at 62.) Thus, Dr. Mayer did not confirm by testing his hypothesis that imidacloprid would accumulate in honeycomb. "'Scientific methodology . . . is based on generating hypotheses and testing them to see if they can be falsified . . . .'" Daubert, 509 U.S. at 593. Dr. Mayer did not apply the rigors of scientific methodology. He generated a testable hypothesis, but did not follow through.

Testing a theory, of course, is not always necessary to show that an expert employed a reliable methodology. See Paoli, 35 F.3d at 759. But an expert must offer "a good explanation as to why his or her conclusion remained reliable" notwithstanding the absence of testing. Id. at 760. Dr. Mayer did not do so in this case.

Instead, Dr. Mayer criticizes Bayer for not testing, "both chemically and biologically, for imidacloprid residues in wax combs and from honey." (Dr. Mayer Aff., Dkt Entry 97-2, at 14.) Of course, it is the proponent of the theory that must test the hypothesis to affirm its reliability. See Paoli, 35 F.3d at 742 (listing "'whether [a hypothesis] can be (and has been) tested'" as a

Daubert factor district courts should take into consideration)(emphasis added). As explained in Caraker v. Sandoz Pharmaceuticals Corp., 188 F. Supp. 2d 1026, 1030 (S.D. Ill. 2001), a proponent of an expert conclusion has the burden of proving that its expert's opinion is reliable, and does this through the "scientific method, i.e., the generation of testable hypotheses that are then subjected to the real world crucible of experimentation, falsification/validation, and replication." While it is evident that Dr. Mayer's hypothesis is testable, the tests were not conducted. Where, as here, an expert's hypothesis is confirmed neither by scientific literature nor by proper testing, the expert's proffered testimony remains "speculative and unreliable." Calhoun v. Yamaha Motor Corp., 350 F.3d 316, 322 (3d Cir. 2003).

Dr. Mayer asserts that he reasonably relied upon the ADPEN results as proof of his theory of imidacloprid accumulation in wax. (Mayer Dep., Dkt. Entry 86-33, at 65.)[13] In the concluding part of his January 12, 2007 affidavit, Dr. Mayer asserts that "[m]y opinion is confirmed by the results from ADPEN. . . . In their analytical tests for imidacloprid in dead bees and comb from the Plaintiffs they found high residues of imidacloprid." (Dkt. Entry 95-2, at 23.)

The initial ADPEN results of more than 100 ppb found in honeycomb, however, lack

---

[13] Q. And how do you know the supers were contaminated with imidacloprid?

A. Because of the result from the Florida lab, ADPEN, that did the residue analysis.

Mayer Dep., Dkt Entry 86-33, at 65.)

grounding in sound testing protocols, and thus cannot form the predicate for Dr. Mayer's conclusions. Furthermore, there is no indication that ADPEN conducted analyses of dead bees after the first round of testing. Therefore, there is no factual basis for the assertion that high levels of imidacloprid were found in dead bees.

Subsequent analyses performed by ADPEN, upon which Dr. Mayer can rely, do not substantiate his theory that imidacloprid accumulates in the wax at levels lethal to bees. With respect to analyses of samples of honey and wax submitted by Mitchell Charles in late 2001 and early 2002, ADPEN found imidacloprid residue of only .83 ppb in honey and 3.2 ppb in wax. (Defs.' Ex. 48, Dkt. Entry 86-54, at 2.) An ADPEN report dated April 4, 2002 for Kenneth Shearon Bee Farms states that imidacloprid was not detected in the wax brood area, and at a level of only .5 ppb in the "Comb from honey area." (Ex. 49, Dkt. Entry 86-55, at 2.) Finally, ADPEN reported in September of 2003 that imidacloprid was not found in two samples of honeycomb from the Robson Honey Company, and was found to be at a level of only 1.3 ppb in a third sample. (Ex. 50, Dkt. Entry 86-56, at 2.)

Dr. Mayer's theory is based upon the assumption that imidacloprid accumulates in the honeycomb over time until it reaches a lethal level. The reported levels of imidacloprid cannot be classified as "lethal."

Not only do the ADPEN results fail to support the accumulation hypothesis, there is no support in the scientific literature for Dr. Mayer's theory. Professor Scott-Dupree gathered

"approximately 30 semi-field and field studies performed since 1998, not only by Bayer scientists but by independent scientists from universities and institutions around the world, who focused on short-and long-term effects of imidacloprid in bee diets."[14] (Scott-Dupree Report, Dkt. Entry 86-40, at 5.) None of the studies revealed any negative impacts in the short or long term in the exposed colonies. (Id.) Furthermore, a study performed in Argentina assessed the side-effects of imidacloprid on honeybees foraging on sunflower grown from Gaucho treated seeds. The study covered an extensive area and ran for 226 days. No side-effects were observed in either the short or long term. (Rogers Report, Dkt. Entry 86-37, at 8.)

Dr. Mayer, at his deposition, acknowledged that he had not found any field studies that had found Gaucho to be lethal to honey bees. (Mayer Dep. at 119.) He also acknowledged that none of the 30 studies that he had reviewed disclosed that bees exposed to Gaucho-treated crops were observed tumbling out of hives, twitching, and then dying – the symptoms described by some of the Plaintiffs in this case. (Mayer Dep. at 120.) Dr. Mayer criticized the studies as "just not large enough." (Id.) But this criticism does not qualify as a good explanation for why his methodology is reliable and should be accepted as a sufficient foundation for his opinions.

In similar circumstances, courts have rejected opinions that were not validated through

[14]Dr. Scott-Dupree conducted a study in 2000 of honeybee exposure to imidacloprid via seed treatment of canola. (Ostiguy Report, Dkt. Entry 86-35,at 8.) Four colonies with sister queens approximately the same age were placed at the easterly edge of canola fields. No differences in behavior, honey production, or bee mortality were observed. (Id.)

the scientific method. For example, in Hamilton v. Emerson Electric Co., 133 F. Supp. 2d 360, 371 (M.D. Pa. 2001), a products liability action, the Hon. James F. McClure, Jr., of this Court found that plaintiff's expert did "not use any discernible methodology to determine that a miter saw contained a defect." Id. at 371. The expert testified that the brake on a miter saw "did not engage as it should have in order to stop the rotation of the blade. Therefore, as the blade was coming up, it continued spinning for several seconds," causing injury to the plaintiff. Id. at 366. The court found the testimony unreliable because, inter alia, plaintiff's expert provided "no evidence that he tested his hypothesis regarding the saw's visual and auditory cues. . . ." Id. at 373. Likewise, Dr. Mayer's failure to test his hypothesis of migration and accumulation of imidacloprid renders his opinions unreliable.

Dr. Mayer's report also suffers from the absence of reliable data concerning the duration of exposure to Gaucho-treated crops or the extent of that exposure. Thus, there is no way to determine the levels of imidacloprid to which foraging bees would have been exposed.

In Kannankeril, the district court excluded an expert's testimony as to the plaintiff's level of exposure to the chemical Dursban because the expert did not know the levels of Dursban or the amount of time plaintiff was exposed. 128 F.3d at 808. The Third Circuit found the district court erred because the expert had reviewed Dursban application records, showing when, how much, and where pesticide had been applied. 128 F.3d at 808. In this case, Dr. Mayer has not

identified when, how much, and where Gaucho has been applied.[15]

Dr. Mayer claims in his report to "personally know that many of the canola fields in the Carrington area of North Dakota were planted with seed treated with Gaucho." (Mayer Report, Dkt. Entry 93-3, at 11.) There is no evidence, however, that all or the majority of the fields within one mile of Plaintiff's apiaries contained Gaucho-treated canola.[16] Dr. Mayer apparently saw a map that identified the fields treated with Gaucho (Dep. Mayer, Dkt. Entry 86-33 , at 149-50), but he has not produced the map or testified to the specific fields that were treated with Gaucho.

Dr. Mayer also stated in his report that "Gaucho was first used in the area in 1995 and a lot was used through 2002."[17] (Mayer Report, at 10.) When asked specifically about the Gaucho treatment, however, Dr. Mayer testified that he did not know how much Gaucho was

---

[15]Another important factor in evaluating an expert's testimony is precision. "Broad generalizations are far more difficult to corroborate than precise statements and have little explanatory power . . . . If severe and varied tests are the best indicator of validity, it follows that broad generalizations that can account for any possible state of affairs, and thus cannot be empirically tested, are not as good." In re TMI Litig. Consolidated Proceedings, No. CIV. 1:CV-88-1452, 1995 WL 848519 (M.D. Pa. Nov. 9, 1995) (citing Bert Black, et al., Science and the Law in the Wake of Daubert: A New Search for Scientific Knowledge, 72 TEX. L. REV. 715, 783-84 (1994).

[16]According to Dr. Mayer, "[h]oneybees forage about one mile in all directions." (Mayer Report, at 13.)

[17]Mr. Rogers observed that "Gaucho® was first used in 1995/1996 and since 2000 use of that product has dropped off sharply in favor of other seed treatment products." (Rogers Report, Dkt. Entry 86-37, at 13.)

used and in what years. (Mayer Dep., Dkt. Entry 86-33, at 152-53.) Without knowledge of the quantities of Gaucho applied and how often, it would be difficult to test Dr. Mayer's theory that exposure to Gaucho-treated canola caused imidacloprid poisoning.[18]

Dr. Mayer has suggested that a large scale field test would be appropriate to confirm his hypothesis. He proposes that forty honeybee colonies be "placed in the center of an area where Gaucho treated canola was planted in all fields or nearly all fields in all directions within one mile from the test colonies." Biological and environmental data would be collected from the test and control colonies weekly for two years, and the fields would be treated with Gaucho for the second growing season. Such a field study, of course, has not been conducted.

Dr. Mayer claims that, by studying Plaintiffs' apiaries throughout North Dakota, he has "conducted a *de facto* large-scale field study on the adverse affects of imidacloprid on honeybees" similar to the one he suggested.[19] (Mayer Aff., Dkt. Entry 96-2, at 23.) Significantly, however, no testing has ever been conducted to confirm the accumulation of imidacloprid in honey supers that Dr. Mayer has theorized. Instead, his entire report rests on

---

[18]Dr. Mayer claims that Bayer could have recommended lower application rates of Gaucho to avoid having imidacloprid present in a plant's nectar and pollen. (Mayer Report at 15.) He does not suggest an application rate, however. Furthermore, he does not indicate the level of imidacloprid to which foraging bees are exposed in Gaucho treated crops. Bayer's experts, however, have cited studies that show the level of imidacloprid is no greater than 7.6 ppb.

[19]In his deposition, Dr. Mayer testified that he does not think that a definitive test has been done on a scientifically controlled bases. (Mayer Dep., at 11.)

an assumption that supers were contaminated with imidacloprid.

Indeed, Dr. Mayer admitted that chemical and biological analyses would be necessary to verify his hypothesis, and that he has not performed these analyses. (Mayer Dep., at 195.) In fact, he is not aware of any studies that have tested for imidacloprid accumulation in wax. (Id. at 125.) Without these chemical and biological analyses, and other scientific studies, Dr. Mayer's opinion that bees were exposed in supers to high levels of imidacloprid simply does not rest upon a reliable methodology.

3. Dr. Mayer's Adverse Effect Theory

Drawing all inferences in Plaintiffs' favor, the evidence of record is that bees may have been exposed to imidacloprid in honey supers at levels of less than 4 ppb.[20] Dr. Mayer testified that imidacloprid at levels around 5 ppb is the correct NOAEC. (Mayer Dep., at 136.) Bayer's experts disagree, arguing that levels of imidacloprid "around 5 ppb" are not sufficient to cause adverse effects, since the generally accepted NOAEC is 20 ppb. If Dr. Mayer's adverse effect theory is not the product of reliable methodology, then his penultimate conclusion that Gaucho-treated canola caused the decimation of Plaintiffs' bee colonies cannot stand.

Dr. Mayer's theory is based on a study performed by Pham-Delegue in 1998

[20]The ADPEN results from March 2, 2002, found imidacloprid in the amounts of .83 ppb in the honey and 3.2 ppb in the wax from Mr. Charles' samples, and the June 12, 2003 results showed 1.3 ppb of imidacloprid in one of three wax samples submitted by Mr. Robson, with no imidacloprid found in the other two.

(erroneously listed by Dr. Mayer has having been issued in 2000),[21] finding a NOEC of 4 ppb, and two studies performed by Colin & Bonmatin, one in 1998 finding a NOEC of 6 ppb and the other in 2000 finding and NOEC of 1-3 ppb. (Mayer Report, at 15.) None of these studies supports Dr. Mayer's theory that the NOAEC for imidacloprid in honeybees is around 5ppb.

First, Pham-Delegue disavowed the results of the first study. In March of 2000, A. Decourtye, under the supervision of Pham-Delegue, found inconsistencies in the original 1998 study. Re-testing the hypothesis, they found a NOEC/NOAEC level of imidacloprid in honeybees of 24 ppb. (Scott-Dupree Report, Dkt. Entry 86-40, at 6.) When asked about the subsequent study finding inconsistences in the first study, Dr. Mayer indicated he was only relying on the first study. (Mayer Dep., Dkt. Entry 86-33, at 28.) Subsequent to these two studies, Pham-Delegue and Decourtye performed additional studies on imidacloprid and honeybees, finding NOEC/NOAEC values between 6 and 48 ppb depending on the physiological state of the bees. (Scott-Dupree Report, Dkt. Entry 84-40, at 6-7.) The 6 ppb finding was based on a single measurement recorded immediately after imidacloprid application in a laboratory bioassay, and would not likely have any biological significance under field conditions. (Id. at 7.) Dr. Mayer's reliance on the first study is thus inappropriate, since Pham-Delegue's second study found inconsistencies in the first, and the later studies found levels of 6

[21]According to Nancy Ostiguy and Dr. Scott-Dupree, the finding of 4 ppb by Pham Delegue occurred in 1998 and not in 2000 as reported by Dr. Mayer. (Ostiguy Report, Dkt. Entry 86-35, at 8; Scott-Dupree Report, Dkt. Entry 86-40, at 6.)

ppb of imidacloprid only after directly feeding imidacloprid to honeybees in a laboratory.

With respect to the Colin & Bonmatin studies conducted in France, Dr. Scott-Dupree discounted their biological significance because they were not performed "in a realistic field situation. . . ." (Scott-Dupree Report, Dkt. Entry 84-40, at 7.) Furthermore, the impact of the imidacloprid on the honeybees was relatively minor. (Id.) In a subsequent study performed in 2004, Colin & Bonmatin inserted 6 ppb of imidacloprid in bee feeders. The result was a significant increase in the number of inactive bees at the feeders, but no difference was observed in the attendance of bees. (Ostiguy Report, Dkt. Entry 86-35, at 8.) In short, none of the reported studies supports Dr. Mayer's theory.[22]

In contrast, there are several studies which resulted in the 20 ppb NOAEC for imidacloprid in honeybees. Dr. Scott-Dupree stated that "[w]hen you review the body of science that is focused on establishing a NOAEC for imidacloprid on honey bees, the value of 20 ppb is clearly the one that is based on the strongest and most credible field tested methodologies." (Scott-Dupree Report, Dkt. Entry 86-40, at 7.) She based her opinion on three studies finding a NOAEC of 20 ppb for imidacloprid in honeybees (Schimdt (2000) and W.H. Kirchner (1998, 2000)). (Id. at 6.) Moreover, she stated that 20 ppb is used by the EPA, PMRA (Pest Management Regulatory Agency-Canada), and similar governmental agencies in Europe, as well as other chemical companies besides Bayer. (Id.) Plaintiffs have not

[22]Dr. Mayer does not discuss these studies in detail in his report, but simply lists them in a table.

challenged the validity of these studies.[23]

Finally, and most significantly, when asked directly whether, in his opinion, 3.2 ppb and lower concentrations of imidacloprid had lethal effects on honeybees (the highest amount of imidacloprid confirmed by the ADPEN analyses), Dr. Mayer responded: "I'm not sure without actually seeing some sort of test data, other than, you know, a topical drop or oral, exactly what would happen if bees were confined on wax with that amount of residue." (Mayer Dep., Dkt. Entry 86-33, at 20.)

Dr. Mayer's analysis did not account for other potential causes of bee morbidity observed by Plaintiffs. Notably, inspections of Plaintiffs' apiaries indicated the presence of "diseases and pests including American foulbrood, European foulbrood, chalkbrood, varroa mite, and small hive beetle." (Scott-Dupree Report, Dkt. Entry 86-40, at 4.) Testing of Plaintiffs' bees and honey conducted by defense experts confirmed the presence of "widespread and multiple viral infections." (Ostiguy Rep., Dkt. Entry 86-35, at 3.) Dr. Mayer's failure to account for these alternative causes of bee morbidity further supports a determination that his methodology is unreliable. Paoli, 35 F.3d at 759.

Research data pertaining to the causal relationship between exposure and adverse impact is important in this type of case. Louderback v. Orkin Exterminating Co., 26 F. Supp. 2d 1298, 1304 (D. Kan. 1998). Dr. Mayer does not relate his opinions to such research data.

[23]At oral argument, Plaintiffs asserted that all of these studies were funded by Bayer. Plaintiffs, however, have not tendered competent evidence supporting this assertion.

There is no evidence of dose (the magnitude or concentration of imidacloprid to which bees were exposed), duration of exposure, or adverse effects. Assuming chronic exposure to the levels of imidacloprid in wax reported by ADPEN, there is no evidence that bee mortality is likely. Moreover, the reports cited by Bayer preclude a finding that Dr. Mayer's conclusions rest on a reliable foundation. Because Dr. Mayer's conclusion does not rest upon a reliable foundation, Bayer's motion to exclude his testimony will be granted.

B. Bayer's Motion for Summary Judgment (Dkt. Entry 86)

At oral argument, Plaintiffs' counsel conceded that if Bayer's motion to preclude Dr. Mayer were granted, Plaintiffs could not withstand Bayer's summary judgment motion. (Oral Arg. Tr. at 49.) Accordingly, judgment will be entered in favor of Bayer.

III. CONCLUSION

For the foregoing reasons, Defendants' Motion to Exclude the ADPEN analyses will be granted with respect to the initial analysis and denied in all other respects. Defendants' Motion to Exclude the Testimony of Daniel Mayer and Defendants' Motion for Summary Judgment will be granted. An appropriate order follows.

s/ Thomas I. Vanaskie
Thomas I. Vanaskie
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

DALE BAUER, CHRIS CHARLES, MITCHELL CHARLES, BODY DALLE, DANIEL GUNTER, d/b/a Gunter Honey, Inc., JUSTIN KENT, d/b/a Kent Honey Bees, Inc., GARY MACKRILL, JOSE MORENO, d/b/a Oro Dulce, Inc., DAVID PARK, DEWEY ROBINSON, KENNETH SHEARON, ELAINE THOMPSON, JEREL JOHNSON, Plaintiffs	:	
v.	:	3:CV-03-1687
	:	(JUDGE VANASKIE)
BAYER A.G., BAYER CORPORATION, Defendants	:	

ORDER

NOW, THIS 20th DAY OF JUNE, 2008, for the reasons set forth in the foregoing memorandum, IT IS HEREBY ORDERED THAT:

1. Defendants' Motion to Exclude the Chemical Analyses of ADPEN (Dkt. Entry 88) is GRANTED as to the initial ADPEN analysis, and DENIED in all other respects.

2. Defendants' Motion to Exclude the Opinion Testimony of Daniel F. Mayer, M.D. (Dkt. Entry 89) is GRANTED.

3. Defendants' Motion for Summary Judgment (Dkt. Entry 86) is GRANTED.

4. The Clerk of Court is directed to enter judgment in favor of Defendants and to mark this matter CLOSED.

s/ Thomas I. Vanaskie
Thomas I. Vanaskie
United States District Judge